Pricing and Reimbursement of Prescription Drugs in German Social Health Insurance*

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Introduction

The current regulation of the market for prescription drugs in German health insurance is under pressure for two reasons. First, third-party payers are unable to control expenditures effectively. Expenditures for prescription drugs are continuously increasing and at a more rapid pace than expenditures in other health care sectors such as ambulatory care and hospital care. Second, third-party payers are incapable of setting incentives for individual physicians to prescribe more efficiently. Physicians prescribe a considerable share of prescription drugs that are more expensive than therapeutic or generic substitutes (Schwabe and Paffrath 2005).

In this paper we develop and present reform scenarios for the regulation of prescription drugs in German health insurance by comparing two important parameters for third-party payers and manufacturers across health care systems. These parameters are regulation of reimbursement and regulation of pricing. Reimbursement and pricing of prescription drugs are regulated extensively in a variety of health care systems. It is obvious that markets for prescription drugs are regulated in health care systems that are predominantly financed by public funds – tax money or social security contributions. However, there is also regulation of prescription drugs in health care systems that are predominantly financed privately – such as the private health insurance sector in the US health care system. The difference is in the level of regulation. As a rule, we find centralized regulation in public systems – either by government itself, agencies authorized by government or by some kind of corporatist intermediaries authorized by law. Centralized regulation implies that the outcome of this regulation – such as reimbursement decisions and prices for prescription drugs – is the same for all third-party payers. In contrast, decentralized regulation prevails in private systems. In the private health insurance sector of the US health care system, individual health plans, pharmaceutical benefits managers or other intermediaries negotiate with manufacturers directly in order to determine reimbursement decisions and individual prices of prescription drugs. As a consequence, the outcome of decentralized regulation may vary between third-party payers.

In this article we compare different levels of regulation across different types of health care systems which determine reimbursement decisions and pricing decisions. Reimbursement decisions determine whether a specific prescription drug will be reimbursed by third-party-payers. Pricing decisions determine the price third-party-payers have to pay for this specific prescription drug. Our comparison includes a variety of different health care systems – one-payer public systems such as the UK, multiple-payer public systems such as Switzerland and multiple-payer private systems such as the private health insurance sector in the US. However, as already indicated by the title of our article, the spotlight of our attention is on reimbursement and pricing decisions in German social health insurance.

The article is organized as follows. In section 2 we analyze reimbursement regulation – both on a centralized and on a decentralized level. In order to illustrate reimbursement regulation on a centralized level we discuss short case studies on Germany, Switzerland and the UK. In order to illustrate reimbursement decisions on a decentralized level we discuss case studies on the private health insurance market in the US and – although only partly applicable – on the social health insurance market in Israel. In section 3 we analyze pricing regulation – again both on a centralized and on a decentralized level. We use the same short case studies to illustrate our findings. Finally, in section 4 we discuss reform scenarios for the regulation of reimbursement and of

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pricing prescription drugs in German social health insurance. We conclude that decentralized pricing and centralized reimbursement is a viable compromise between consumer protection and a more competitive and cost-effective market for prescription drugs in German social health insurance – and other similar markets for prescription drugs.

Regulation of reimbursement

Reimbursement of prescription drugs in any third-party-payer system is not equivalent to market approval by regulatory agencies such as the Food and Drug Administration (FDA) in the US. In any third-party-payer system a variety of instruments to determine the reimbursement status of prescription drugs is being used (Greß et al. 2005b). We distinguish between instruments that are used on a centralized level and instruments that are used on a decentralized level.

Centralized regulation

The results of our review of instruments used to determine the reimbursement status of prescription drugs on a centralized level are displayed in Table 1. Most European countries indeed use centralized regulation in addition to market approval. The effectiveness of new prescription drugs is assessed by a centralized institution. Moreover, theses institutions are also increasingly required to assess the cost-effectiveness of new prescription drugs. However, the assessment of cost-effectiveness very rarely leads to the exclusion of prescription drugs from reimbursement. The outcome of (cost-) effectiveness assessments result in country-specific formularies which sometimes are augmented by lists of prescription drugs to be excluded form reimbursement.

Although these results point toward common trends in centralized regulation, details of regulation differ considerably between countries. This finding can be illustrated by short case studies of centralized regulation in Germany, Switzerland and the UK (Greß et al. 2005a).

In German social health insurance, reimbursement decisions are made on a central level by a corporatist body – the Federal Joint Committee. The Federal Joint Committee consists of representatives of sickness funds, health care providers and patient organizations. Representatives of patient organizations are allowed to attend. However, they are not allowed to vote. It was only in 2004 that the legislator allowed this corporatist body to exclude prescriptions drugs from reimbursement. These decisions need to be based on a (negative) clinical effectiveness assessment of the prescription drug concerned. Reimbursement of all other prescription drugs with market approval is mandatory for all social health insurers in Germany. In contrast to most other countries, there is no country-specific formulary in Germany. The new German Institute for Quality and Efficiency in Health Care is responsible of conducting health technology assessments and for giving recommendations to the Joint Committee. However, German legislation rules out the use of cost-effectiveness assessments as a criterion for determining the reimbursement status of prescription drugs.

In Switzerland, the reimbursement status of prescription drugs is also determined on a centralized level. Formally, the Swiss Federal Office of Public Health is in charge of all reimbursement decisions. The Federal Office has established the Federal Drug Commission to give recommendations for reimbursement decisions. The Federal Drug Commission

Table 1

Instruments for centralized regulation in EU-15 and EFTA countries: Reimbursement

Countries	Assessment of effective–ness	Assessment of cost-effective-ness	Country-specific formulary
Austria	X	++	X
Belgium	X	++	X
Denmark	X	++	X
Finland	X	++	X
France	X	++	X
Germany	X	–	–
Greece	X	+	X
Ireland	X	++	X
Italy	X	++	X
Netherlands	X	++	X
Norway	X	++	X
Portugal	X	++	X
Spain	X	+	X
Sweden	X	++	X
Switzerland	X	+	X
UK	X	+++	X

Luxembourg, Liechtenstein and Iceland not included.
X Implemented.
– Not implemented.
\+ Emerging assessment of cost-effectiveness.
++ Assessment of cost-effectiveness is obligatory but not a criterion for exclusion.
+++ Strong assessment of cost-effectiveness is also used as a criterion for exclusion.

Sources: Dickson et al. 2003; Greß et al. 2005b; Stafinski and Menon 2003.

consists of physicians, pharmacists, academics, representatives of health insurers, of patient organizations and of manufacturers. In contrast to Germany, health insurers may reimburse only those prescription drugs that are listed on the country-specific formulary. The Federal Drug Commission lists new prescription drugs if the assessment of clinical effectiveness has been positive. Moreover, the assessment results in a classification of new prescription drugs based on their degree of innovation. Although legislation requires assessments to be based also on cost-effectiveness of new prescription drugs, assessment of cost-effectiveness so far is not a criterion for exclusion from reimbursement in Switzerland (Cranovsky et al. 2000).

Similar to Germany and Switzerland, in England and Wales the reimbursement status of prescription drugs is determined on a centralized level by the National Institute of Clinical Excellence (NICE). Decisions are made by the Appraisal Committee which consists of health care providers, representatives of manufacturers, patient organisations, representatives of regional health authorities und health economists. In contrast to Switzerland, NICE does not list all prescription drugs that are eligible for reimbursement. Regional health authorities are required to reimburse drugs which are recommended by NICE and may also reimburse all other drugs that are not excluded by NICE. Only very rarely does NICE exclude prescription drugs form reimbursement completely. However, it is quite common that NICE limits the use of drugs to certain indications and populations subgroups. The use of cost-effectiveness as a decision criterion for reimbursement is quite advanced in England and Wales (Devlin and Parkin 2004).

Decentralized Regulation

Reimbursement decisions usually are made on a centralized level. In countries with one-payer health care systems such as England or France there is no alternative to this approach. Diverging reimbursement decisions for the same payer – e.g. in different regions – are difficult to imagine. However, there is an alternative to centralized regulation in multi-payer systems such as Switzerland or Germany. If there are multiple third-party payers – and enrollees of these payers may switch to other payers on a regular basis – it is quite conceivable that reimbursement decisions are made on a decentralized level. As a consequence, individual payers make individual reimbursement decisions. This practice is rather common in the US private health insurance market and – at least to some extent – in the social health insurance market in Israel.

In fact reimbursement decisions in Israel are made on a centralized level as well as on a decentralized level. However, there is some latitude for individual health insurers. This flexibility is limited to prescription drugs that can be substituted generically or therapeutically. As a consequence, health insurers in Israel have individual formularies for these products. However, stand-alone patents need to be reimbursed by all health insurers (Sax 2001).

In contrast to the social health insurance market in Israel, there is no centralized regulation at all for reimbursement decisions on the private health insurance market in the US. However, this does not mean that market approval of prescription drugs by the FDA is equivalent to reimbursement by private health insurers. It does mean that health insurers are free to determine insurer-specific formularies. In doing so, health insurers are not restricted by centralized institutions. As a consequence of the managed care revolution in the 1980s and 1990s, most health insurers in the US have developed insurer-specific formularies (Frank 2001). The design of insurer-specific formularies varies considerably. Three types of insurer-specific formularies – the main instruments of decentralized reimbursement regulation – can be distinguished (Huskamp et al. 2003):

1. *Open* Formularies. Open Formularies contain prescription drugs which are preferred by the health insurer. However, physicians may also prescribe other products which the health insurer will also reimburse.
2. *Closed* Formularies. Closed Formularies contain all prescription drugs which are reimbursed by the health insurer. If physicians prescribe other products the health insurers will not reimburse them.
3. *Incentive* Formularies. Incentive Formularies are closed formularies that allow physicians and patients more choice for generic and therapeutic substitutes. Co-payments for patients are higher for branded generics and me-too patents.

Private health insurers have become reluctant to use closed formularies since they are unpopular with consumers. Now they mostly use a mix of open and closed formularies. Moreover, incentive formularies

have become more pervasive recently (Peters et al. 2001). It is not transparent which criteria private health insurers in the US use for designing insurer specific formularies. Variations in the use of cost-effectiveness assessments are high although a non-binding standard for the development of evidence-based formularies was established in the year 2000 (Garbner 2004; Neumann 2004).

For the new Medicare drug coverage starting in 2006 – which can also be provided by private health insurers – legislation explicitly allows closed formularies for generic and therapeutic substitutes (Atlas 2004). As a consequence, regulation in this part of the US health care system is now quite similar to regulation in Israel.

Regulation of pricing

We have shown that third-party-payers in any kind of health care system use a variety of instruments to regulate reimbursements of prescription drugs. In this section we analyze the instruments third-party-payers use to regulate the pricing of reimbursable prescription drugs. Again we distinguish between instruments that are applied on a centralized level and instruments that are applied on a decentralized level.

Centralized regulation

Table 2 illustrates the fact that there is a variety of instruments being used in order to regulate pricing of prescription drugs on a centralized level. Many countries use direct price regulation. Direct price regulation means that manufacturers are not free to determine prices freely. Either third-party-payers determine prices by themselves or third-party-payers negotiate with manufacturers about prices. In most countries prices are determined by the use of external reference prices of the product. Some countries such as France and Switzerland allow surcharges on the price if – as a result of (cost-) effectiveness assessments – the product is known to be very innovative.

Other countries – such as Germany and the Netherlands – use a more indirect and less restrictive approach to regulate prices. In principle, manufacturers are free to set prices for all products that are reimbursable. However, in these countries therapeutic and generic substitutes are clustered into groups on a centralized level. For each of these groups a reference price is determined. Generic and therapeutic reference prices need to be distinguished. Generic substitutes are pharmaceuticals with the same active ingredients and formulation. Therapeutic substitutes are pharmaceuticals with different active ingredients and formulations but with comparable therapeutic effects for the same indication (Danzon et al. 2005).

Third-party payers will reimburse only the reference price. If physicians prescribe products with a price above the reference price, patients need to pay the surcharge out-of-pocket. Manufacturers have a strong incentive for charging prices that are equivalent to the reference price. If the price were below the reference price, only third-party-payers and – if user charges are proportional to price – patients would profit from lower prices. On the other hand, patients are very sensitive to surcharges for products with a price above the reference price (Pavcnik 2002; Schneeweiss et al. 2002a).

Traditionally, manufacturers in Germany were free to set prices for reimbursable prescription drugs.

Table 2

Instruments for centralized regulation in EU–15/EFTA countries: Pricing

Countries	Direct price regulation	Internal reference prices	Free pricing	Control of profits	External reference prices
Austria	X	–	X	–	X
Belgium	X	X	–	–	X
Denmark	–	X	X	–	X
Finland	X	–	–	–	X
France	X	X	–	–	X
Germany	–	X	X	–	–
Greece	X	–	–	–	X
Ireland	X	–	–	–	X
Italy	X	X	–	–	X
Netherlands	–	X	X	–	X
Norway	X	–	–	–	X
Portugal	X	X	–	–	X
Spain	X	X	–	–	X
Sweden	X	X	–	–	X
Switzerland	X	–	–	–	X
UK	X (Generics)	–	X (Patents)	X (Patents)	–

Luxembourg, Liechtenstein and Iceland not included.
X Implemented.
– Not implemented.

Source: Greß et al. 2005b.

However, free pricing was restrained by the internal reference price system that was adopted in 1989. Although there have been several short periods of direct price controls of the German government to cut overall prices, free pricing is unrestricted for stand-alone patents. Reference prices are applicable for generic as well as for therapeutic substitutes in Germany. While generic substitutes are adequately covered by the reference price system, this is not true for therapeutic substitutes. Only since the 2004 health care reform, has the legislator again allowed the Joint Federal Committee to establish groups of therapeutic substitutes – including me-too patents. This provision was suspended from 1996 to 2003.

In contrast to Germany, there is no free pricing for prescription drugs in Switzerland. The Swiss Federal Office of Public Health and manufacturers negotiate prices for new prescription drugs. Negotiations start if (cost-) effectiveness assessment of the new product (see section 2) has been positive. Prices are based on external ex-factory reference prices in Denmark, Germany, the Netherlands and the UK. If the new prescription drug is shown to be very innovative, the Federal Office adds a surcharge to the external reference price – up to 20 percent for a maximum of 15 years. If manufactures are not willing to supply their products with the price suggested by the Federal Office, the product will not be listed on the country-specific formulary.

Although manufacturers are free to set prices for patented prescription drugs in the UK, they face a unique method of indirect price regulation. The Pharmaceutical Price Regulation Scheme (PPRS) stipulates that manufacturers have to lower prices if their profits exceed a threshold. If manufacturers fall below these thresholds they may raise prices of their products. At the moment the thresholds are 21 percent for return on capital and six percent for return on sales. However, the margin of tolerance is quite substantial – between 40 percent and 140 percent. As a consequence, manufacturers need to lower prices if their return on capital exceeds 29.4 percent and if return on sales exceeds 8.4 percent. They may raise prices if return on capital falls below 8.4 percent and if return on sales falls below 2.4 percent (Association of the British Pharmaceutical Industry and Department of Health 2005).

Decentralized regulation

Although centralized regulation of pricing is as pervasive as centralized regulation of reimbursement, there is also a variety of instruments to regulate pricing of prescription drugs on a decentralized level. As a consequence, the price of the same prescription drug may vary considerably between third-party-payers, although it would be the same for all third-party-payers if it were regulated on a centralized level. In Israel price competition is limited to generic and therapeutic substitutes (see section 2). The market for social health insurers is highly concentrated in Israel. There are only four competing social health insurers in Israel. The biggest – Clalit – has a market share of about 60 percent. As a consequence, price competition for substitutes is high and third-party-payers are quite successful in negotiating rebates with manufacturers (Sax 2001).

Decentralized regulation of pricing also leads to price competition for prescription drugs on the private health insurance market in the US. Multiple third-party payers are free to negotiate prices with manufacturers of prescription drugs. If third-party payers are not satisfied with the results of these negotiations they are also free not to list these products on their insurer-specific formularies. On the other hand manufacturers can also decide not to supply their products if they are not satisfied with the price offered by a third party. In contrast to health care systems with centralized pricing regulation, manufacturers may find other third-party payers who are willing to pay a higher price.

Decentralized regulation of pricing on the private health insurance market in the US is not equivalent to negotiations between individual third-party payers and individual manufacturers. Although this setting might occur, mostly third-party payers have outsourced the negotiating process to PBMs – pharmaceutical benefit managers (Goff 2002). PBMs perform a variety of tasks for third-party payers in the US. Most importantly, PBMs assist in the design of insurers-specific formularies, negotiate discounts and rebates with manufacturers of prescription drugs and organize retail services for enrollees (GAO 2003).

Actually third-party payers and PBMs negotiate discounts, not prices, with manufacturers. The size of discounts usually depends on the prescription volume of the product. The more physicians prescribe the product – and the more patients consume it – the higher are the discounts. As a consequence, PBMs negotiate discounts form manufacturers in return for a preferred status on the insurer-specific formulary

and an increase in market share (Danzon et al. 2005).

Information about the size of discounts is difficult to obtain. However, it is estimated that PBMs can negotiate rebates of up to 35 percent of the standard prize for patents (US DHHS 2002). PBMs keep 10 to 30 percent of the savings for themselves (Pennsylvania Health Care Cost Containment Council 2004). Rebates are tied closely to insurer-specific formularies and to contractual relations with physicians. Third-party payers and PBMs set incentives for physicians as well as for enrolees to increase the use of preferred prescription drugs. Physicians are either obliged to prescribe them if they are employed by a third-party payer. The prescription of preferred drugs can also be part of the contract between third-party payers and physicians. Moreover, patients often pay lower user charges for preferred prescription drugs if third-party payers use incentive formularies.

As a consequence, price competition is highest for generic substitutes and lowest for stand-alone patents. Concentration of the US pharmaceutical industry has increased since the beginning of the managed care revolution. Manufacturers try to counteract the strong position of third-party payers and PBMs. Moreover, manufacturers of prescription drugs were able to recover some of their revenues losses due to discounts to PBMs by raising the standard prize of their products. Thus, uninsured individuals and non-negotiating third-payers have to pay an even higher price for prescription drugs (Frank 2001).

Table 3

Levels of regulation: Reimbursement and pricing

		Reimbursement	
		Centralized	Decentralized
Pricing	Centralized	Social health insurance in Germany *Scenario #1*	–
	Decentralized	Social health insurance in Israel Medicare (2006) *Scenario #2*	Private health insurance in US *Scenario #3*

Source: Greß et al. 2005b.

Future regulation of prescription drugs in German social health insurance

Sections 2 and 3 have shown that several features of pricing and reimbursement of prescription drugs in German social health insurance are peculiar. First, only in German social health insurance is market approval of new products almost equivalent to reimbursement by third-party payers. Second, only in 2004 did legislation make it possible to exclude prescription drugs from reimbursement with a negative effectiveness assessment. Third, in contrast to other health care systems, the legislator has not introduced the use of cost-effectiveness assessments for reimbursement decisions. Fourth, manufacturers of prescription drugs are free to set prices for their products – although free pricing has been restricted by internal reference pricing for generic substitutes since 1989 and for therapeutic substitutes since 2004.

Since expenditures for prescription drugs in German social health insurance are constantly increasing, we assume that the legislator will continue to adjust the regulation of reimbursement and the pricing of prescription drugs. Table 3 points out three reform scenarios that are based on our analysis in sections 2 and 3. In scenario #1, the legislator will improve the existing system of centralized reimbursement and centralized pricing. In scenario #2 reimbursement decisions will remain on a centralized level while pricing decisions will be decentralized – similar to the system of social health insurance in Israel or Medicare 2006 in the USA. If the legislator adopts scenario #3, both reimbursement and pricing decisions will be decentralized – similar to the private health insurance system in the US. Below we discuss the consequences for patients, manufacturers and third-party payers for each of the three reform scenarios.

Scenario #1: Centralized reimbursement and centralized pricing

This reform approach assumes that the legislator will follow a path-dependent approach. Two main features of regulation reimbursement and pricing will remain unchanged. First, regulation will continue to be centralized. Second, pricing regulation will continue to be indirect rather than direct. As a consequence, the legislator will primarily improve the effectiveness of internal reference prices. Moreover, the legislator will introduce the use of cost-effectiveness assessments

for reimbursement decisions. In fact the obligatory use of cost-effectiveness assessments for reimbursement decisions was included in an early draft of the 2004 health care reform – but did not make it into the final draft of the reform law.

If reimbursement decisions in German social health insurance are made on the basis of cost-effectiveness assessments, two approaches for implementation will be feasible. First, only prescription drugs with a positive assessment will be listed on a country-specific formulary. Other prescription drugs will be excluded from reimbursement. Second, only prescription drugs with a positive assessment will be excluded from reference pricing. All other drugs will be subject to therapeutic reference pricing. As a consequence, prescription drugs with a negative cost-effectiveness ratio will continue to be reimbursed – albeit only on the level of the reference price. Given the German proclivity toward reference pricing, we consider the latter approach to be more feasible. As a consequence, there will be free pricing for stand-alone patents and internal reference pricing for generic and therapeutic substitutes.

What will be the consequence of this approach? Patients will be eligible to full reimbursement for stand-alone patents and for reimbursement of the reference price of products that are generically or therapeutically equivalent. If groups are homogenous, effects on patients are negligible (Schneeweiss et al. 2002b). However, therapeutic referencing is more controversial than generic referencing. It treats prescription drugs with different ingredients as perfect substitutes although effectiveness and/or side-effects might be different for at least some patients (Danzon et al. 2005). If groups are heterogeneous with respects to effectiveness and/or side effects and manufacturers are unwilling to lower their price to the reference price, some patients will face increased co-payments. Even worse, manufacturers might take their products from the market entirely.

Consequences for manufacturers in this setting also depend very much on the ability to establish homogenous therapeutic reference groups on a centralized level. If groups are homogenous, manufacturers face increased incentives to invest in innovative products rather than in me-too products. However, if groups are heterogeneous, manufacturers face disincentives to invest in innovations at all since they might not be able to recover their costs for research and development from the lower reference price.

Effects on third-party payers are unclear. Third-party payers are less interested in prices of prescription drugs than in expenditures for prescription drugs. Expenditures are determined by price, volume and the composition of prescriptions. Prices for stand-alone patents in our setting probably will increase while prices for me-too patents will decrease. Prices for generics will not change very much. If prescription behavior does not change, expenditures decline. However, if physicians switch to prescribing stand-alone patents rather than me-too patents or generics, expenditures will not go down. Third-party payers have no influence on the outcome either way since they are unable to set incentives for physicians to prescribe more efficiently.

Scenario #2: Centralized reimbursement and decentralized pricing

In this scenario, third-party payers in German social health insurance will be able to negotiate with manufacturers about discounts and market shares for generic and therapeutic substitutes. In principle reimbursement decisions will remain centralized as described in scenario #1. However, in contrast to scenario #1, third-party payers will only be obliged to reimburse stand-alone patents and at least one prescription drug per therapeutic or generic group. As a consequence, third-party payers will be able to establish insurer-specific incentive formularies. As a result, there might be no user charges at all for preferred products. In contrast, patients will either have to pay hefty surcharges for therapeutic or generic substitutes that are not part of the insurer-specific formulary or – more consistently – will have to pay the full price for these substitutes out-of-pocket.

However, decentralized negotiations between third-party payers and manufacturers about rebates in return for preferred status on insurer-specific formularies only make sense if third-party payers are able to create sufficient incentives for physicians to increase market shares of preferred products. This is impossible in the current setting of contractual relations between third-party payers and physicians in German social health insurance. In principle, all third-party payers need to contract all willing providers. Selective contracting is limited to very few experimental schemes. Thus, third-party payers are not able to contract selectively. As a consequence, they are not able to gain competitive advantages. However, decentralization of pricing decisions is all about gaining competitive advantages, which only makes sense in a more com-

petitive setting (Greß 2004). Only in a more competitive setting will individual third-party payers be able to design contractual arrangements with physicians to promote prescription drugs with a preferred status.

In this scenario, price competition for therapeutic and generic substitutes will increase. Prices for stand-alone patents are not influenced. Patients will benefit from lower user-charges. Moreover, if third-party payers are able to influence prescription behavior of physicians successfully, patients can ultimately also benefit form lower health care expenses of third-party payers by paying lower premiums. For manufacturers, the consequences of this scenario depend very much on their product portfolio. Price competition will increase for manufacturers that only produce therapeutic and generic substitutes. However, if manufacturers are able to offer a large variety of products, they will probably have a good bargaining position. As a consequence, concentration will increase. The position of producers of stand-alone patents will not change very much. Therefore, incentives for the development of innovative products are even more pronounced than in scenario #1 – if groups for generic and therapeutic substitutes are homogenous.

Scenario #3: Decentralized reimbursement and decentralized pricing

This scenario assumes that third-party payers are free to determine reimbursement and pricing of prescription drugs. However, prescription drugs will still be part of the standardized benefits package of German social health insurance. Individual third-party payers are responsible for making sure that the provision of prescription drugs is adequate. Thus, third-party payers decide which prescription drugs to reimburse in order to fulfill this requirement. As a consequence, third-party payers will also be able to exclude stand-alone patents from reimbursement.

In this scenario third-party payers will attain additional instruments for product differentiation. In return for lower premiums and/or lower co-payments, third-party payers will be able to offer "no-frills" packages of prescription drugs – limited to generic and therapeutic substitutes and some stand-alone patents. "Premium" packages might include more choice of substitutes and stand-alone patents in return for higher premiums and/or higher co-payments. Consequences for patients are rather ambiguous. On the one hand, more choice would be available. As a consequence, consumer choice becomes more important. However, financial consequences for patients might be substantial if stand-alone patents need to be paid out-of-pocket in case of sudden ill health.

Implications for manufacturers in this scenario are also very pronounced. In contrast to scenarios #1 and #2, in this scenario price competition would also apply to stand-alone patents. However, from the experience on the private health insurance market we know that third-party payers are very reluctant to exclude stand-alone patents from reimbursement. Manufacturers of stand-alone patents might even link stand-alone patents to other products of their portfolio. As a consequence the bargaining position of manufacturers that produce only therapeutic or generic substitutes will decrease and concentration of the market will increase.

Conclusions

In this paper we analyze regulation of two important parameters for third-party payers and manufacturers of prescription drugs in a variety of health care systems. First, regulation of reimbursement determines whether a specific prescription drug will be reimbursed by third-party payers or will only be available to patients with a 100 percent co-payment. Second, regulation of pricing determines the price third-party payers have to pay for this specific prescription drug. We distinguish between centralized regulation and decentralized regulation.

We have found that the centralized regulation of reimbursement and pricing prevails in most health care systems. Regulation in German social health insurance stands out as rather unique. In contrast to other countries using centralized regulation, market approval is equivalent to reimbursement. So far the legislator does not allow country-specific formularies. Moreover, cost-effectiveness may not be used to exclude prescription drugs from reimbursement. Pricing regulation in German social health insurance is less restrictive than in other countries, too. Manufacturers are free to determine prices. However, internal referencing sets incentives for manufacturers not to exceed reference prices.

Centralized regulation of reimbursement and prices in German social health insurance is increasingly being placed under pressure. First, expenditures for prescription drugs are increasing constantly and more rapidly than expenditures in other health care

sectors. Third-party payers are unable to control expenditures. Second and more importantly, physicians prescribe a considerable share of prescription drugs that are more expensive than therapeutic or generic substitutes.

Our comparison of different levels of regulation leads to three reform scenarios. In scenario #1 prescription drugs will be excluded from reimbursement if they provide an unfavorable ratio between marginal costs and marginal benefits. If these prescription drugs are reimbursed at all, the price will be the same as for generic or therapeutic substitutes. However, in this scenario third-party payers will have a hard time setting incentives for physicians to control expenditures.

Third-party payers will have a stronger bargaining position in reform scenario #2, which is based on decentralized pricing and centralized reimbursement – similar to social health insurance in Israel. Third-party payers will be able to negotiate with manufacturers about discounts and market shares for genetic and therapeutic substitutes. In contrast to scenario #1, third-party payers will be obliged to reimburse stand-alone patents and at least one prescription drug per therapeutic or generic group. As a consequence, third-party payers will be able to establish insurer-specific incentive formularies. If groups for generic and therapeutic substitutes are homogeneous, incentives for the development of innovative products are even more pronounced than in scenario #1. Moreover, if third-party payers have more instruments to manage care, they will also be able to control expenditures more effectively.

Reform scenario #3 is based on decentralized pricing and decentralized reimbursement – similar to the private health insurance market in the US. Third-party payers will attain additional instruments for product differentiation. However, the consequences for patients are rather ambiguous. Although consumer choice becomes more important, financial consequences for patients can be substantial. Therefore, reform scenario #2 is a viable compromise between consumer protection and a more competitive and cost-effective market for prescription drugs in German social health insurance and other similar markets for prescription drugs.

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